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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

7590 05/27/2005

WENDEROTH LIND & PONACK LLP
2033 K STREET NW
SUITE 800
WASHINGTON, DC 20006

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/393,168	ISHIKAWA ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

20

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskel et al (US Patent # 3851051) in view of Tanner et al (US patent # 5569466).

Miskel et al, see Example 1 column 6, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility (diphenhydramine). No dispersion stabilizer and oil material or oil soluble material is present. Further, Miskel et al, see Example 50 column 20, teach a soft capsule comprising a water-soluble dietary fiber (apple pectin), a material of limited oil solubility (glycerin) and a fat and oil material or oil-soluble material (vitamin E). Lastly, Miskel et al, see Example 43 column 19, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil solubility (sodium saccharine). No dispersion stabilizer and fat and oil material or oil-soluble material is present. High stability is disclosed (column 1 line 21).

However, Miskel et al do not teach a homogeneous mixture of the medicinal liquid in the soft capsule.

Tanner et al teach fill compositions for soft gel capsules (title) comprising an active agent dissolved or suspended in a carrier liquid (abstract). Tanner et al teach homogenization of actives and solubilizing agents (column 4 lines 47-70 and 65-66). Water is disclosed (column 3 line 61).

Art Unit: 1616

It would have been obvious to one of ordinary skill to make a soft gel capsule comprising citrus pectin to achieve high stability in view of Miskel et al. As to the claimed homogenization, Tanner et al teach that homogenization is well known in the art of making a soft gel capsule. One of ordinary skill in the art would recognize that homogenization provides a stable mixture.

Applicants argue that the Miskel et al capsule contains a rigid gel system comprising a gel-lattice matrix. However, Miskel et al disclose a soft capsule having a water-containing solution or suspension of active ingredient in the fill (column 3 lines 43-35). Miskel et al further teach a soft gelatin capsule containing a fluid or semi-fluid fill composed of the gel-lattice matrix as a carrier for the aqueous solution or suspension (column 3 lines 49-51). Thus, although the gel system may be rigid, the capsule contents as a whole remain fluid or semi-fluid. Applicants argue that a drying operation is not required in their invention, however, applicants are claiming a composition, not a method of making. Applicants argue that water is not required in their invention, but they do not claim an anhydrous composition. Applicants state that pectin increases the amount of active ingredients in the aqueous solution or suspension. However, the relevance of this observation is unclear. Applicants also argue that that the maltitol syrup in Tanner et al is incompatible with the Miskel et al invention. However, Tanner et al is only cited for its teaching of homogenization of capsule contents.


No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1616

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Edward J. Webman at telephone number 571-272-0633.


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500